#### VACCINE INFORMATION STATEMENT

# Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

#### 1 Why get vaccinated?

Influenza ("flu") is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:

- · fever/chills
- · sore throat
- · muscle aches
- fatigue
- · cough
- · headache
- · runny or stuffy nose

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year thousands of people in the United States die from flu, and many more are hospitalized.

#### Flu vaccine can:

- · keep you from getting flu,
- · make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

# 2 Inactivated and recombinant flu vaccines

A dose of flu vaccine is recommended every flu season. Children 6 months through 8 years of age may need two doses during the same flu season. Everyone else needs only one dose each flu season.

Some inactivated flu vaccines contain a very small amount of a mercury-based preservative called thimerosal. Studies have not shown thimerosal in vaccines to be harmful, but flu vaccines that do not contain thimerosal are available.

There is no live flu virus in flu shots. They cannot cause the flu.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against three or four viruses that are likely to cause disease in the upcoming flu season. But even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Flu vaccine cannot prevent:

- flu that is caused by a virus not covered by the vaccine, or
- · illnesses that look like flu but are not.

It takes about 2 weeks for protection to develop after vaccination, and protection lasts through the flu season.

## Some people should not get this vaccine

3

Tell the person who is giving you the vaccine:

- If you have any severe, life-threatening allergies.
   If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine contain a small amount of egg protein.
- If you ever had Guillain-Barré Syndrome (also called GBS).

Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.

· If you are not feeling well.

It is usually okay to get flu vaccine when you have a mild illness, but you might be asked to come back when you feel better.



#### Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get a flu shot do not have any problems with it.

#### Minor problems following a flu shot include:

- soreness, redness, or swelling where the shot was given
- hoarseness
- · sore, red or itchy eyes
- · cough
- · fever
- · aches
- · headache
- · itching
- · fatigue

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

More serious problems following a flu shot can include the following:

- There may be a small increased risk of Guillain-Barré Syndrome (GBS) after inactivated flu vaccine. This risk has been estimated at 1 or 2 additional cases per million people vaccinated. This is much lower than the risk of severe complications from flu, which can be prevented by flu vaccine.
- Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Ask your doctor for more information. Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

### Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction.
   Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5

# What if there is a serious reaction?

#### What should I look for?

 Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

#### What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get the person to the nearest hospital. Otherwise, call your doctor.
- Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

### 6

# The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

#### 7

#### How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC's website at www.cdc.gov/flu

# Vaccine Information Statement Inactivated Influenza Vaccine

08/07/2015

42 U.S.C. § 300aa-26



Introducing the

#### **Massachusetts Immunization Information System**

# MIIS

#### Fact Sheet for Parents and Patients



The MIIS is a new statewide system to keep track of immunization records for you and your family. These records list the vaccinations (shots) you and your children get to protect against measles, chickenpox, tetanus, and other diseases. The goal is to make sure that everyone in Massachusetts is up-to-date with their shots and that your records are available when you need them – such as when your child enters school, when you need emergency medical help, or when you change healthcare providers.

#### What is the MIIS?

- A computerized system that collects and stores basic immunization information for people who live in Massachusetts.
- A secure and confidential system, as required by Massachusetts law.
- A system that is available for people of all ages, not just children.

#### How will it help me?

The MIS:

- Helps you and your family get the best care wherever you go for your healthcare.
- Makes sure that you and your children don't miss any shots or get too many.
- Can print a record for you or your children when you need it — if you move, if your doctor retires, or when your child starts school or camp.

#### Why is this important?

As you know, the schedule of shots needed to keep healthy can be very complicated. The MIIS:

- Helps your healthcare provider keep track of which shots are due and when they should be given.
- Keeps all your immunization records together for you, your family, and your healthcare provider.
- Provides proof of vaccination for your children.
- Helps prevent outbreaks of disease like measles and the flu in your community.
- Keeps shot records safe during natural disasters such as flooding or hurricanes.





### What information is kept in the MIIS?

- A list of shots that you or your children have received as well as any that you or your children get in the future.
- Information needed for safe and accurate immunization of each patient, such as:
  - » Full name and birth date.
  - » Gender (male or female).
  - » Mother's maiden name (for children).
  - » Address and phone number.
  - » Provider office where each shot is given.

## How does this information get into the system?

- Information about children is added when a child is born or when a child gets his or her first shots.
- Your healthcare provider can add your records or your family's records if they are not already in the MIIS.

### Who has access to my records?

- The Department of Public Health (DPH) uses modern technology to make sure that all information entered into the MIIS is kept secure and confidential.
- The information in the MIIS is only available to:
  - » Healthcare providers or others ensuring appropriate immunization, as authorized by DPH.
  - » Schools.
  - » Local boards of health.
  - » DPH, including the WIC program, and other state agencies or programs that provide education and outreach about vaccines to their clients.
  - » Studies specially approved by the Commissioner of Public Health which meet strict legal safeguards.

### What if I don't want my information shared?

- You have the right to limit who can see your information.
- To limit who can see your information, you need to fill out the 'Objection or Withdrawal of Objection to Data Sharing' form which you can get from your healthcare provider.
- If you decide to limit who can see your information, your current healthcare provider will be able to see the shots they have given to you or your children, but may not be able to see your complete immunization history.
- If you decide to limit who can see your information, you will not have access to all of the benefits of the MIIS, like sharing your immunization records with schools and emergency rooms, and a complete record of shots in a single place.
- You can change your mind (decide to share or not share your information) at any time.

How can I get more information?

Please visit our website at **www.mass.gov/dph/miis**, contact the Massachusetts Immunization Program directly at 617-983-6800 or 888-658-2850, or ask your healthcare provider for more information.

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